

EUROPEAN REGULATIONS FOR PLASTIC FOOD CONTACT MATERIALS

An update on the Regulation (EU) 10/2011

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Food contact materials - Introduction

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**The Framework Regulation :
(EU) 1935/2004 and GMP 2023/2006**

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(EU) 10/2011 for plastic food contact materials

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Responsibility in the Supply Chain – Declaration of Compliance



WHAT ARE FOOD CONTACT MATERIALS

Packaging

- Consumer packaging
- Industrial Packaging : **FIBC's**

Food Machinery Industry

- Conveyor belts, filters, membranes, pipes, etc.

Kitchen Utensils

- Cutlery, plates, cups
- Food appliances



UNDERSTANDING THE RISK



Consumer risk:

- Daily exposure to hazardous substances
- Endanger human health on longer term

Commercial risk:

- No compliance = illegal products
- Recalls : Image damage on brands, products and corporation itself



THE FRAMEWORK REGULATION (EU) 1935/2004

- **Mandatory for all food contact materials** including packaging materials, kitchen utensils and equipment in the food processing industry
- **Applicable for all kind of materials:** plastics, recycled plastics, paper & board, glass, metals, ceramics, inks, colorants, silicones, rubbers, etc.



THE FRAMEWORK REGULATION (EU) 1935/2004

Article 3 of EU 1935/2004:

Materials and articles may not transfer their substances to food in quantities which could:

- endanger human health
- bring about an unacceptable change in the composition of the food
- bring about a deterioration in the organoleptic characteristics thereof.

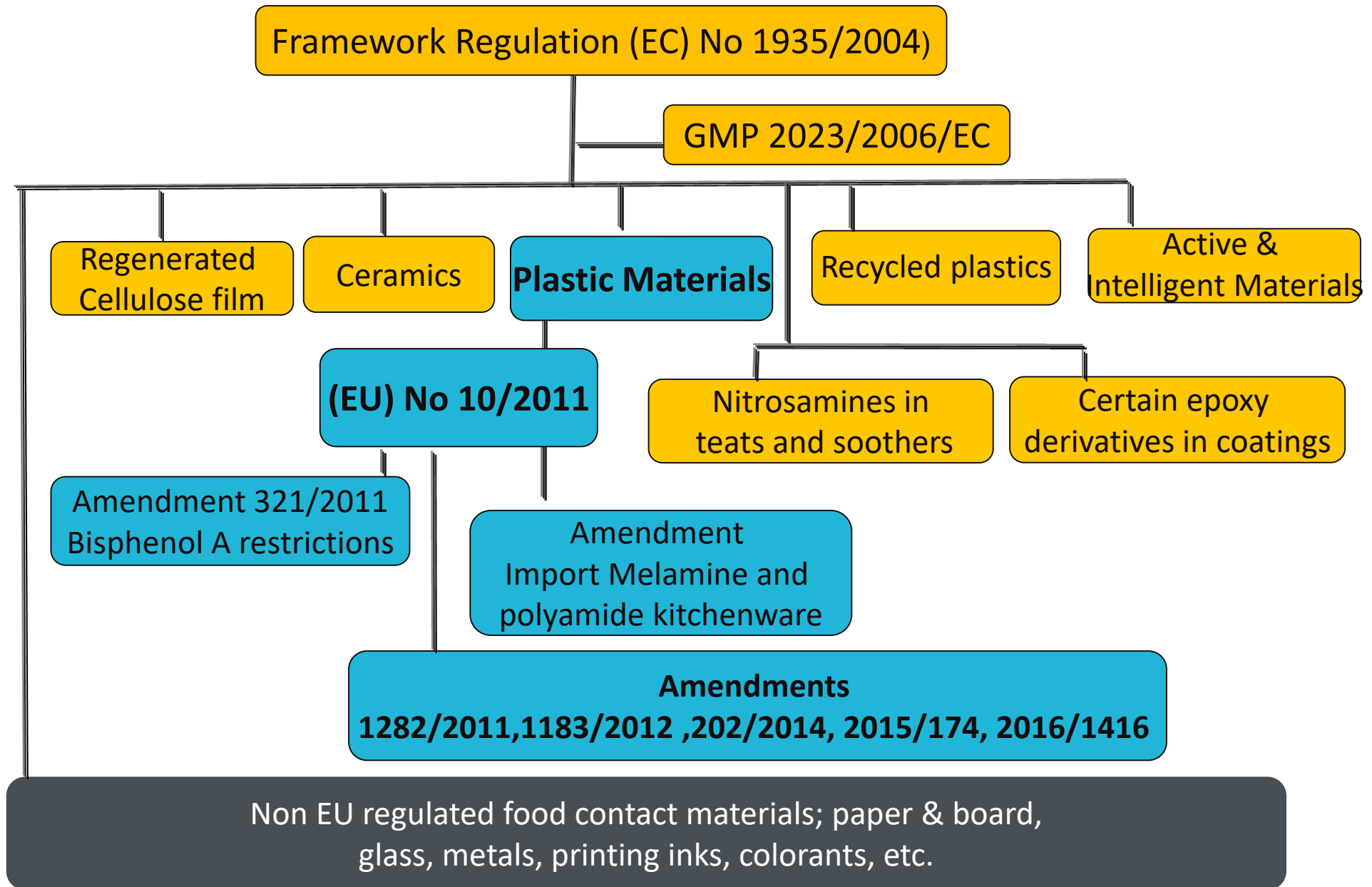


(EU) 2003/2026 - GOOD MANUFACTURING PRACTICES

- Aspects of **quality assurance & quality control** that guarantee that articles are consistently produced and controlled
- **Documentation - Traceability**
- **Applies to all sectors and stages** of manufacturing, processing and distribution of materials
- ISO 22000, FSSC22000, BRC



EUROPEAN LANDSCAPE FOR FOOD CONTACT MATERIALS



PLASTIC REGULATION (EU) 10/2011

- Most comprehensive regulation in Europe
- Only substances included in the positive list (monomers & additives) are authorized to be used in the manufacturing process
- Restrictions on overall and specific migration of substances
- Compliance Testing procedures
- Set out rules for a Declaration of Compliance

Covered by this regulation:

- Monolayer materials, multilayer materials bound by adhesives, can be colored, coated and/or printed



PLASTIC REGULATION (EU) 10/2011

MIGRATION LIMITS

Overall Migration Limit (OML)

- Measure for inertness of material
- Sum of all substances that can migrate, limit 10 mg/dm²

Specific Migration Limit (SML)

- Defines the quantity of one specific substance that migrates into food/food simulant
- Limit is specified in Union list, based on toxicological evaluation by EFSA

Maximum permitted quantity (QMA)

- Applies to the residual content of the component into the food contact material. Specified in Union list for some substances

Compliance with all of these limits is required to be compliant with Regulation (EU) 10/2011



PLASTIC REGULATION (EU) 10/2011

But adhesives, printing inks, colorants, coatings:

- Covered by national legislations
- Contribution of substances to the migration into the food needs to be taken into account to fulfill the requirements of the (EU)10/2011
- **Need to fulfill the safety requirements of Regulation (EC)1935/2004**



PLASTIC REGULATION (EU) 10/2011

Migration Testing – Food simulants

- Used to simulate various food types for testing purposes
- Various food categories are linked to the different simulants

Food type	Food simulant
Aqueous food	10% Ethanol (simulant A)
Acidic food	3% Acetic acid (simulant B)
Alcoholic food ($\leq 20\%$)	20 % Ethanol (simulant C)
Semi-fatty food Alcoholic food ($> 20\%$)	50 % Ethanol (simulant D1)
Fatty food	Vegetable oil (simulant D2)
Dry food	MPPO (simulant E)

(1)	(2)	(3)					
Reference number	Description of food	Food simulants					
		A	B	C	D1	D2	E
03	Chocolate, sugar and products thereof						
	Confectionery products						
03.01	Chocolate, chocolate-coated products, substitutes and products coated with substitutes					X/3	
03.02	Confectionery products:						
	A. In solid form:						
	I. With fatty substances on the surface					X/3	
	II. Other						X
	B. In paste form:						
	I. With fatty substances on					X/2	

PLASTIC REGULATION (EU) 10/2011

Migration testing – Test conditions:

- **Overall migration:**
 - 7 standard test conditions
 - 2 alternative test conditions (high temperature)
- **Specific migration:**
 - Combination of contact times and temperatures
 - 4 standardized conditions for exposure > 30 days
 - Frozen: 10 days 20°C
 - Refrigerated: 10 days 40°C
 - Storage ≤ 6 months RT: 10 days 50°C
 - Storage > 6 months RT: 10 days 60°C

Test	Contact time & temperature	Intended food contact conditions
OM1	10d at 20° C	Frozen, refrigerated
OM2	10d at 40° C	Long term storage including short term heating
OM3	2h at 70° C	Short term heating
OM4	1h at 100°	High temperature application
OM5	2h at 100° C or at reflux or 1 h at 121° C	High temperature application up to 121° C
OM6	4h at 100° C or at reflux	Any food contact conditions with food simulant A,B,C at temp > 40° C
OM7	2h at 175° C	High temperatures application with fatty foods



6TH AMENDMENT: REGULATION (EU) 2016/1416

The most important changes:

- 14 new substances evaluated by EFSA and added to the positive list
- Substances with FCM No. 871, 1031 and 1052 listed in Annex I for which a restriction (50 ppb) on the migration of oligomers (< 1000 Dalton) is laid down in that Annex shall only be used if a suitable method of analysis for determining the migration of oligomers can be provided. In future EFSA will provide test methods.
- Definitions of rubber not yet included
- Substitute simulants introduced (95 % ethanol and iso-octane, MPPO in case foreseeable use > 100°C) in case testing with simulant D2 is technical not feasible). But still no rules on test conditions!
- Generic migration limit has been repealed (>> 200 substances without SML)



6TH AMENDMENT: REGULATION (EU) 2016/1416

- Changes to the specific migration limits for metals:
 - aluminum : 1 mg/kg (newly added)
 - Zinc: 5 mg/kg (instead of 25)
 - Nickel: not yet included (to be expected in 7th amendment)
- Assignment of MPPO as food simulant for fresh and chilled fruit and vegetables (CF = 10)
- Assignment of simulant B (besides simulant A) for fresh peeled or cut vegetables/fruit in case the pH < 4.5
- Transitional provisions:
 - Into force as on September 14th 2016
 - Plastic materials complying with the (EU)10/2011 as applicable before Sep 14th may be placed on the market until September 14th 2017
 - The following provisions shall apply from September 14th 2018:
 - Migration limits for Zinc and Aluminum
 - The adjusted simulants for vegetables and fruits



UPCOMING CHANGES

- EU commission notified draft regulation to WTO to lower the SML for Bisphenol A: from 0.6 mg/kg to 0.05 mg/kg
 - Also applicable to varnishes and coatings
 - Expected entry into force: 2017
- Upcoming guidance on migration testing – postponed several times
- 7th amendment :
 - Revised limit for Nickel (0.02 mg/kg)
 - Modernize the scientific approach in evaluation studies: NIAS, Exposure, etc.

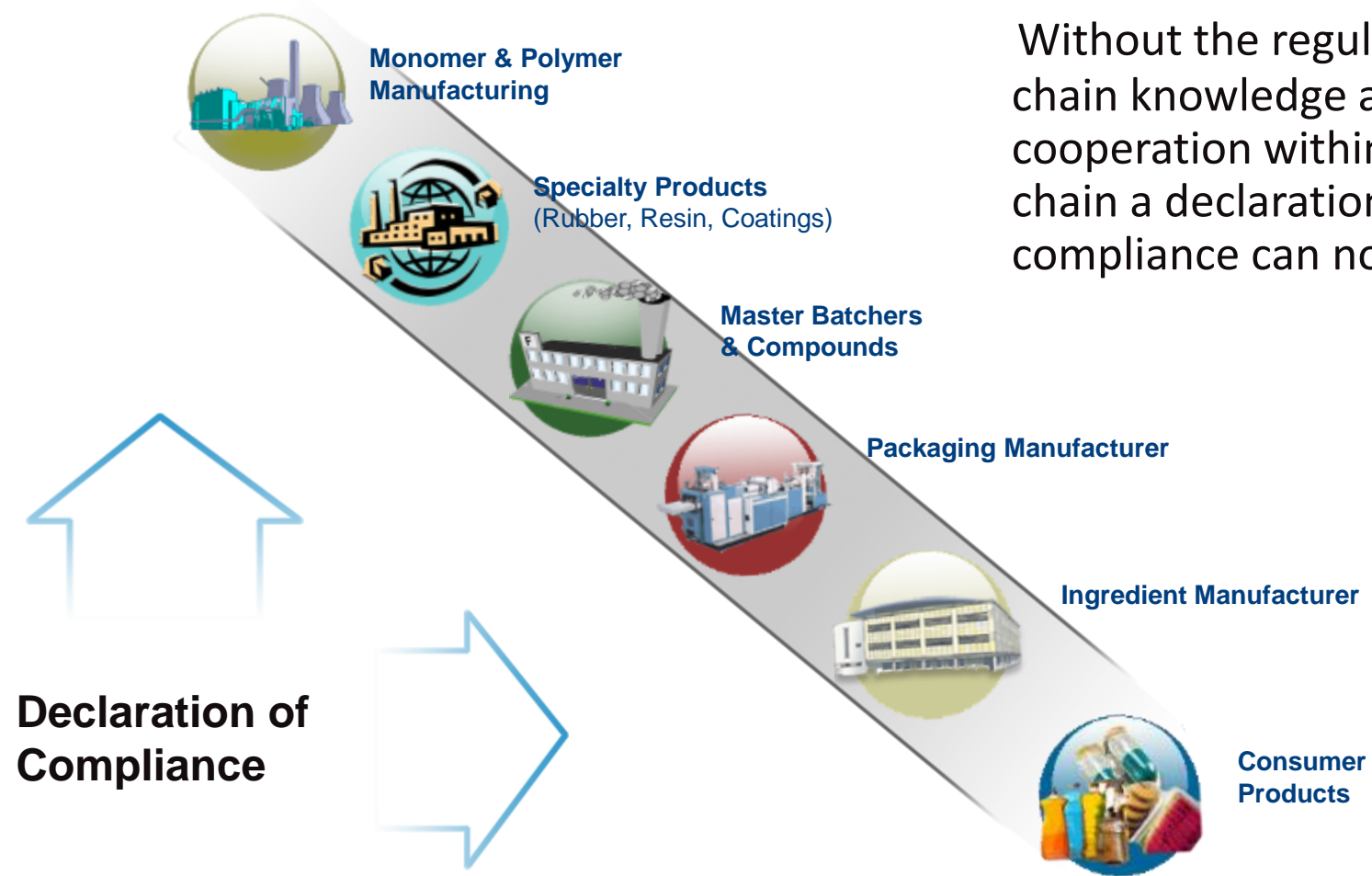


RESPONSIBILITY IN THE SUPPLY CHAIN – DECLARATION OF COMPLIANCE

- Plastic food contact materials shall be accompanied by a written **Declaration of Compliance** stating that they apply with the rules applicable to them
- Provides the next one in the **supply chain** with relevant information necessary to establish or check compliance of the article
- • Applies to the final article but also to intermediate stage up to starting substances
- A new DoC should be issued if there are changes in the composition or production of the product that bring about changes in the migration
- **Supporting documentation** (evidence) are all in-house documents on which DoC is based and needs to be available to enforcement authorities
- Adequate information for non-plastic parts (adhesives, printing inks, coatings)



SUPPLY CHAIN RESPONSIBILITY



**THANK YOU FOR YOUR
ATTENTION**



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